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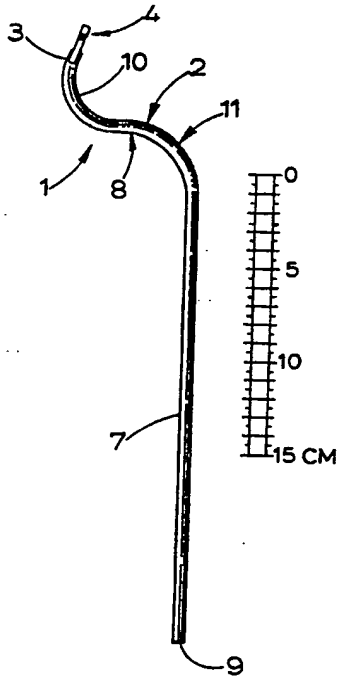
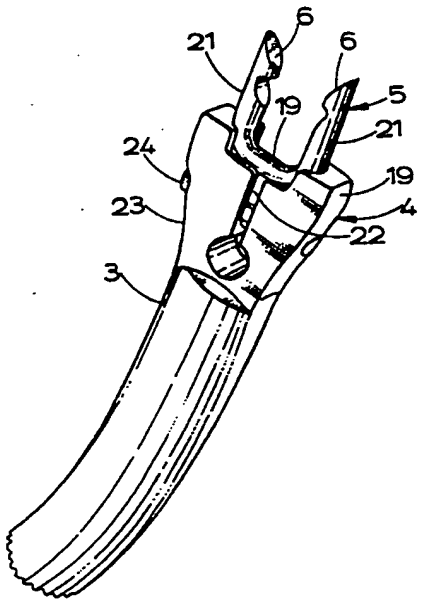
(54) Title: STAPLE APPLICATOR FOR USE IN THE SURGICAL TREATMENT OF FEMALE STRESS INCONTINENCE

(57) Abstract

A staple applicator suitable for use in treating female stress incontinence by surgery comprises an elongate probe (2) of a suitable surgical material, the probe (2) being formed at a first extremity (3) thereof to carry releasably a surgical staple (5). The probe is of S-shape in the first end region (8) adjacent to the first extremity (3), and is dimensioned such that when the first extremity (3) holding a staple (5) is inserted into the vagina (12) and upwardly through an incision (15) in the vaginal wall of a patient in the lithotomy position, the opposite, second extremity (9) of the probe can be positioned vertically below the first extremity (3) and clear of the patient to enable an orthopaedic mallet to be impacted on the second extremity (9) to urge the first extremity (3) upwards to apply the staple into the pubic ramus/pubis, the staple then being released from the first extremity to allow withdrawal of the probe. The probe can be provided with a staple retainer (Figures 6, 7) in the form of a retractable strip (31).





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STAPLE APPLICATOR FOR USE IN THE SURGICAL TREATMENT OF FEMALE STRESS INCONTINENCE

This invention relates to a staple applicator for use in treating female stress incontinence. The applicator enables a staple to be inserted into the superior pubic ramus/pubis through a vaginal incision, thereby lifting the vaginal muscle upwards to re-attach the bladder to the pubis. In particular the applicator enables such a novel colposuspension to be conducted without the need for any incision in the lower abdomen.

The colposuspension is performed with the patient in the lithotomy position and the inventive staple applicator is shaped to permit initial insertion of the staple through the vaginal incision and then to enable an impact to be applied to the staple to secure the staple in position.

CLINICAL PROBLEM

Many women who undergo childbirth in the normal passage of delivery stretch their pelvic floor muscles to an extent that results in urinary incontinence. The sphincter apparatus in the female is much weaker than in the male and continence relies on the bladder maintaining its position as an intra-abdominal organ. The bladder (and other pelvic organs) are supported by the pelvic floor muscles and when these muscles are weakened so the bladder and urethra (and sphincter muscles) descend through the pelvic floor. A physical stress such as coughing, sneezing, laughing, climbing stairs or even walking can increase the pressure within the abdomen and pelvis and force a volume of urine through the sphincter muscles. This is called stress incontinence.

OPERATIONS FOR STRESS INCONTINENCE

The known successful procedures for stress incontinence rely on repositioning and supporting the bladder. The overall success rate

in good hands has been approximately 80%. In 1956 Burch described his operation called the colposuspension. This involves an incision of 20 cm in the lower abdomen and dissection down to the bladder which is itself mobilised (dissected free from surrounding structures) and re-attached to the inner surface of the pubis with 4 to 6 sutures between the vaginal muscle wall (the colpos) and the pectinate line (a ligament which will allow penetration by a suture needle). In view of the amount of dissection etc., a catheter is inserted for a period of 7 to 10 days.

More recently, Stamey in 1981 described his operation which also repositioned and supported the bladder but with much less surgical trauma. With the anaesthetised patient in the lithotomy position (lying on the back with the legs bent up and supported in slings) two small 1 cm incisions are made in the lower abdomen and a long blunt needle passed down through the abdominal wall and through the vaginal muscle at the level of the neck of where the urethra is attached. Nylon slings are threaded onto the needle on either side and when the nylon is tied at the top, the vaginal muscle is suspended from the anterior abdominal wall.

The problems encountered with this procedure have been: infection of the dacron patches which spread the load of the forces applied to the tissues, "cheese wiring" the nylon is tied too tight, and breaking nylon, which sometimes lasts for only two years in the body.

THE STAPLE COLPOSUSPENSION

I have devised a novel colposuspension which can conveniently be termed a 'staple colposuspension'.

The patient is anaesthetised and placed in the lithotomy position. A balloon catheter is inserted into the bladder and this identifies the level of the bladder neck. Two 1 cm incisions are made through the mucosa (lining layer of the vagina) at a distance of

a few centimetres from the entrance thereto. The staple attached to my inventive applicator is placed into one of the vaginal incisions and the vaginal muscle is lifted upwards. The staple is inserted into the superior pubic ramus/pubis by tapping the opposite end of the staple applicator with an orthopaedic mallet.

This procedure is repeated with a second staple inserted through the other incision whereby the vaginal muscle is used to make a sling to support the bladder.

According to one aspect of the invention a staple applicator suitable for use in treating female stress incontinence by surgery comprises an elongate probe of a suitable surgical material, the probe being adapted at a first extremity thereof to carry releasably a surgical staple, the probe being of substantially S-shape in the first end region adjacent to said first extremity, the probe being dimensioned such that when the first extremity holding a staple is inserted into the vagina and upwardly through an incision in the vaginal wall of a patient in the lithotomy position, the opposite, second extremity of the probe can be positioned substantially vertically below said first extremity and clear of the patient to enable an orthopaedic mallet to be impacted on the second extremity to urge the first extremity substantially upwards to apply the staple into the pubic ramus/pubis, the staple then being released from the first extremity to allow withdrawal of the probe.

The curve of the S-shape that is closest to said first extremity is desirably of smooth shape because that portion of the probe enters the patient, and is preferably of substantially round transverse cross-section, but the other 'curve' of the S, which does not enter the patient, could be of more angular shape if desired. However, a relatively smoothly curved shape will in general provide greater rigidity to transmit the mallet blow to the staple.

The shank of the probe which is contiguous with the S-shaped portion is preferably of sufficient length to extend below the table on which the patient is supported to enable the mallet to be applied from beneath the table without the mallet contacting the table or the patient.

Thus, the length of the probe as measured between the first and second extremities is typically 320 mm.

The probe is conveniently constructed from a rod of medical grade stainless steel to which an elongate socket member is welded at one end to provide the first extremity.

A second aspect of the invention comprises a staple applicator in accordance with the first aspect of the invention in combination with a surgical staple, the first extremity carrying the surgical staple with the prongs of the staple extending away from the first extremity.

The staple prongs are preferably each formed with barbs.

The barbs are preferably created by forming recesses of wedge shape in the prongs when the staple is formed by bending of thick wire material. Such a staple has been used previously, but in a larger size.

A staple applicator and a modification thereof both in accordance with the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a side elevation of the applicator,

Figure 2 is a perspective view of the first extremity of the probe showing the socket to receive a staple,

Figure 3 is a view similar to Figure 2 but showing the staple held in the socket,

Figure 4 schematically shows a patient in the lithotomy position and with the applicator inserted through an incision in the vaginal wall to the operative position in which a blow is applied to the applicator for securing the staple,

Figure 5 is a side elevation of a staple,

Figure 6 is a side elevation of a modified applicator provided with a staple retainer, and

Figure 7 is a view of the staple retainer looking from the left in Figure 6.

With reference to Figures 1 and 4, the staple applicator 1 comprises an elongate probe 2 bent from a rod of surgical steel and having welded thereto at a first extremity 3 a socket member 4 of surgical steel, the socket member 4 being shaped to hold releasably a surgical staple 5, as shown in Figure 3, with the prongs 6 of the staple directed axially away from the first extremity 3.

The probe comprises a first end region 8 of substantially S-shape contiguous with a straight shank 7 which terminates in a second extremity 9 of the probe. The probe is substantially planar, that is the S-shaped portion 8 lies in substantially the same plane as the shank 1.

The S-shaped portion 8 comprises a first curved portion 10 of radius of curvature substantially 25 mm contiguous with a second curved portion 11 of opposite hand to the first curved portion 10, and of radius of curvature substantially 55 mm. The first curved portion 10 extends through an arc subtending substantially 110° whereas the second curved portion 11 extends through an arc subtending substantially 90°.

As shown in Figure 4, the dimensions of the first curved portion 10 are such as to enable the socket member 4 holding a staple to be introduced into the vagina 12 of a patient 13 supported in the lithotomy position on a table 14, the staple being pushed through an incision 15 made in the vaginal wall at a position spaced at about 30 mm from the entrance 16 to the vagina. The shank 7 will initially be held in the position indicated by the line 7^1 in Figure 4, and then moved progressively to the position shown by bold lines in Figure 4 as the first curved portion 10 is moved substantially in an arc about the radius of curvature of the first portion.

It will be appreciated that the arcuate shape of the first curved portion 10 facilitates insertion of the staple to the operative position with minimal disturbance to the vaginal wall itself. As the staple is urged upwards it carries with it part of the vaginal muscle to lift up the bladder 16.

With the probe in the position shown in bold outline in Figure 4, a mallet blow can be applied to the second extremity 9 of the probe in the direction indicated by the arrow X, that is, substantially along a line connecting the second and first extremities 9, 3 so as to drive the staple generally upwardly into the pubic ramus/pubis. This procedure is repeated with a second staple inserted through a further incision, not shown, in the vaginal wall positioned adjacent to incision 15, so as to create a sling from the vaginal muscle which holds the bladder in a more normal, raised position.

Although it is convenient that the portion 11 is smoothly curved as shown, since the portion 11 does not enter the patient, that portion could be of a more angular shape if desired, but the curved shape shown is easy to form and provides rigidity to the probe for transmitting the force of the mallet blow from the second extremity 9 to the staple.

The length of the shank 7 is desirably such that the second extremity 9 is well clear of both the patient and the underside of

table 14.

The socket member 4 is conveniently machined from plate material, but it could be formed integrally with the probe, by forging for example. The socket member 4 is of substantially truncated triangular shape with the base 17 formed with a slot 18 of semicircular cross-section to receive snugly the bridge 19 of a staple of the form shown in Figure 5. The slot 18 opens outwards, in the direction away from the first extremity 3 of the probe. Base 17 is shaped to define a pair of castellations 19 which are directed away from the first extremity 3 and are each formed in respective inwardly opposing side faces with semicircular recesses 20 to receive the respective limbs 21 of the staple in the region where the limbs 21 connect with the bridge 19.

In order to provide the socket member 4 with a degree of resilience to enable the grip imparted by the castellations 19 on the staple to be adjusted, the socket member 4 is formed with a longitudinal through-slot 22 terminating in a transverse through-drilling 23.

A set screw 24 extends in the plane of the plate from which member 4 is formed, and enables adjustment of the relative spacing of castellations 19. The screw 24 is adjusted such that the staple is firmly held by the member 4 yet such that once the staple 5 has been secured in place the probe can simply be removed by firm pressure to part the socket member 4 from the gripping staple.

Whilst the staple can be of any convenient form, the staple shown in Figure 5 is preferred. The illustrated staple is a smaller version of a staple designed by Howemedica/London Hospital, but other designs of staple would be possible.

The staple 5 is bent from medical grade stainless steel in wire form, the limbs 21 being sharpened at their free ends 25, and recesses 26 being cut in confronting sides of the limbs 21 to define respective barbs 27.

It will be appreciated that the staple is firmly held in the socket 4 by the the castellations 19 with the limbs 21 directed away from the first extremity. The staple cannot pivot about the bridge 19 because it is held against such pivoting by the engagement between the limbs 21 and the walls of recesses 20.

Figure 6 shows a modification to the applicator of Figure 1, and corresponding reference numerals have been applied in Figure 6 to parts corresponding to those of Figure 1. The applicator of Figure 6 comprises an elongate probe 2 of similar shape to that of Figure 1, but the applicator also incorporates a staple retainer 30 for assisting in holding a staple 5 captive in the first extremity 3 of the probe during manoeuvring of the probe.

The retainer 30 comprises a bent length of spring steel strip 31 having a first extremity 32 of a reduced width corresponding to the inside spacing between the limbs 21 of staple 5 such that the strip extremity 32, as shown in Figure 6 is capable of biassing the staple 5 against the first extremity 3 of the probe.

The strip 31 is rigidly secured to a straight length of tube 33 which is axially slidable on the shank 7 of the probe 2, and to a collar 34 which is also slidable on probe 2. The collar 34 is positioned initially on bend 11, and a strip support face 35 of the collar is shaped to control the direction of free end portion 36 of the strip so as to provide a small resilient biassing of the staple 5 towards extremity 3.

In use the surgeon can use the probe to carry the staple to the position of insertion, and then the tube 33 is drawn down the shank 7 thereby drawing the strip 31 away from extremity 3, to disengage the strip extremity 32 from the staple 5.

CLAIMS

1. A staple applicator suitable for use in treating female stress incontinence by surgery comprises an elongate probe (2) of a suitable surgical material, the probe (2) being adapted at a first extremity (3) thereof to carry releasably a surgical staple (5), the probe being of substantially S-shape in the first end region (8) adjacent to said first extremity (3), the probe being dimensioned such that when the first extremity (3) holding a staple (5) is inserted into the vagina (12) and upwardly through an incision (15) in the vaginal wall of a patient in the lithotomy position, the opposite, second extremity (9) of the probe can be positioned substantially vertically below said first extremity (3) and clear of the patient to enable an orthopaedic mallet to be impacted on the second extremity (9) to urge the first extremity (3) substantially upwards to apply the staple into the pubic ramus/pubis, the staple then being released from the first extremity to allow withdrawal of the probe.

2. A staple applicator as claimed in claim 1 characterised in that probe comprises a length of rod which has been bent to define the S-shaped first end region (8).

3. A staple applicator as claimed in claim 2 in which the probe is constructed from a rod of medical grade stainless steel to which an elongate socket member is welded at one end to provide the first extremity.

4. A staple applicator as claimed in any of the preceding claims characterised in that the length of the probe as measured between the first and second extremities is greater than 200 mm.

5. A staple applicator as claimed in any of the preceding claims characterised by a releasable staple retainer (30) adapted to retain the staple captive to the first extremity.

6. A staple applicator as claimed in claim 5 characterised in that the staple retainer (30) comprises a strip of resilient material of which one end (32) is adapted to engage with a staple (5) and to be retracted from the staple.

7. A surgical staple applicator as claimed in any one of the preceding claims in combination with a surgical staple (5), the first extremity (3) carrying the surgical staple (5) with prongs (6) of the staple extending away from the first extremity.

8. The combination of claim 7 characterised in that the staple prongs are each formed with barbs (27).

9. A method of inserting a surgical staple using a surgical staple applicator as claimed in claim 1.

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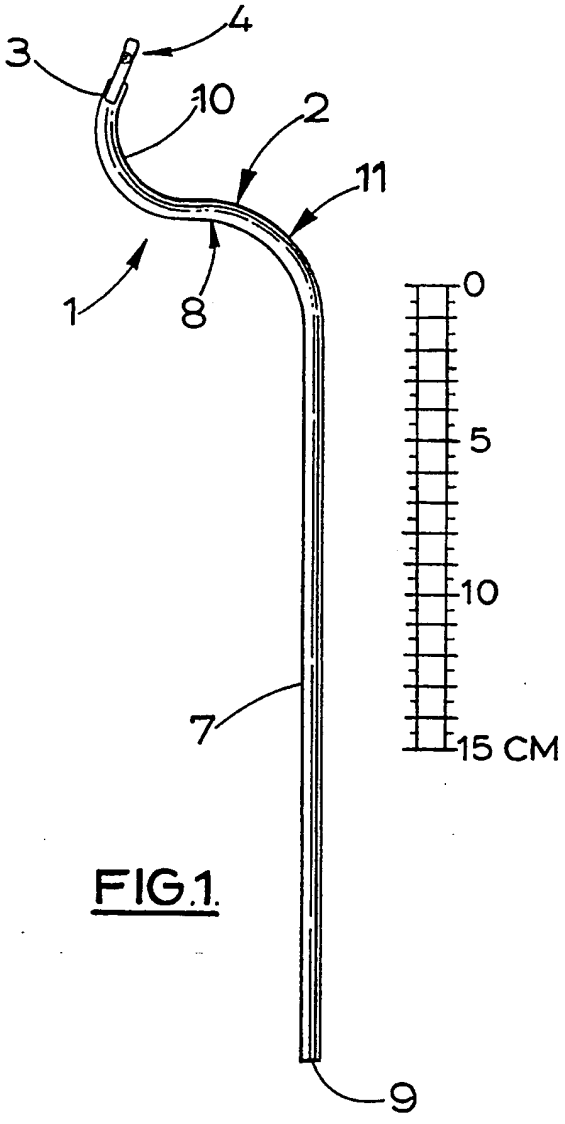

FIG.1.

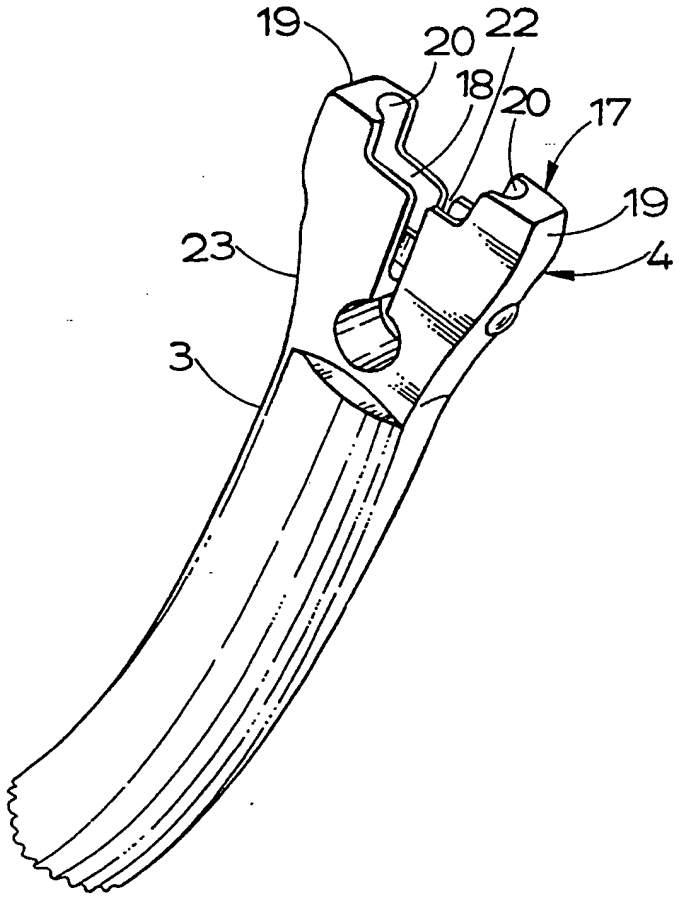

FIG.2.

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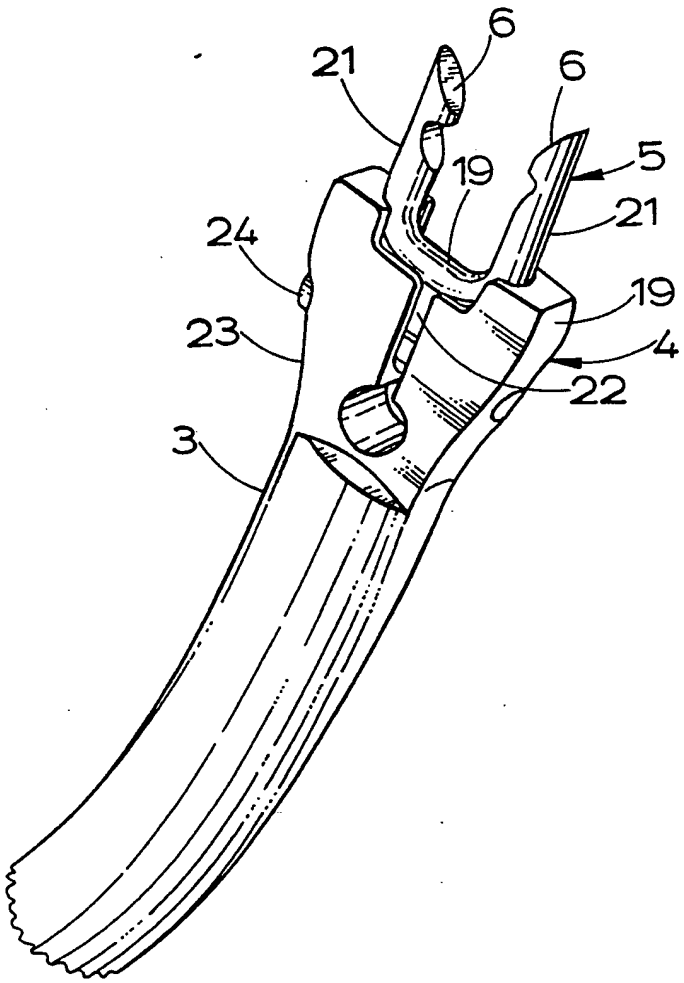

FIG.3.

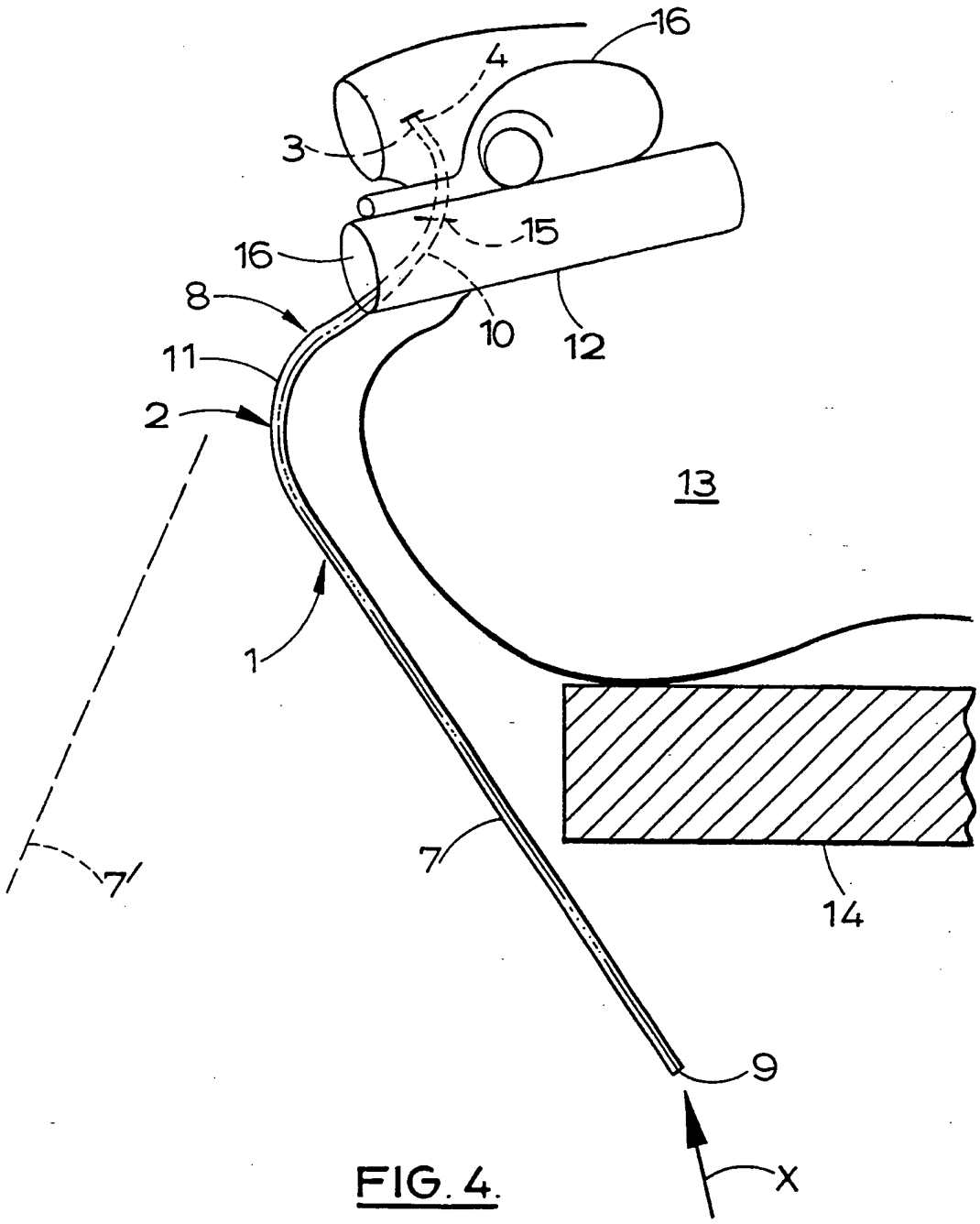

FIG. 4.

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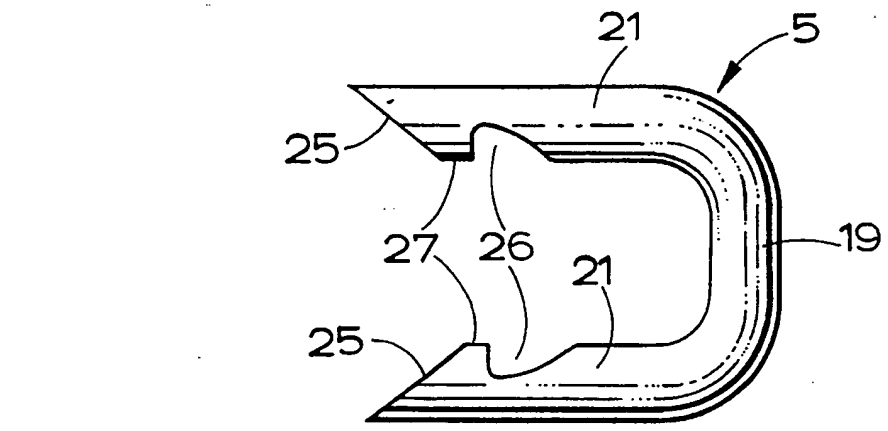

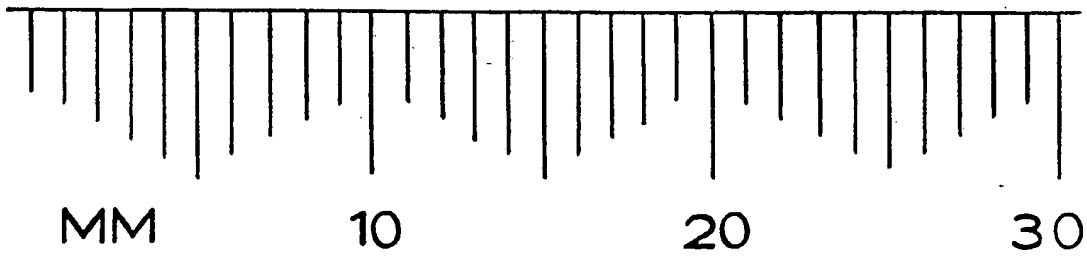

FIG.5.

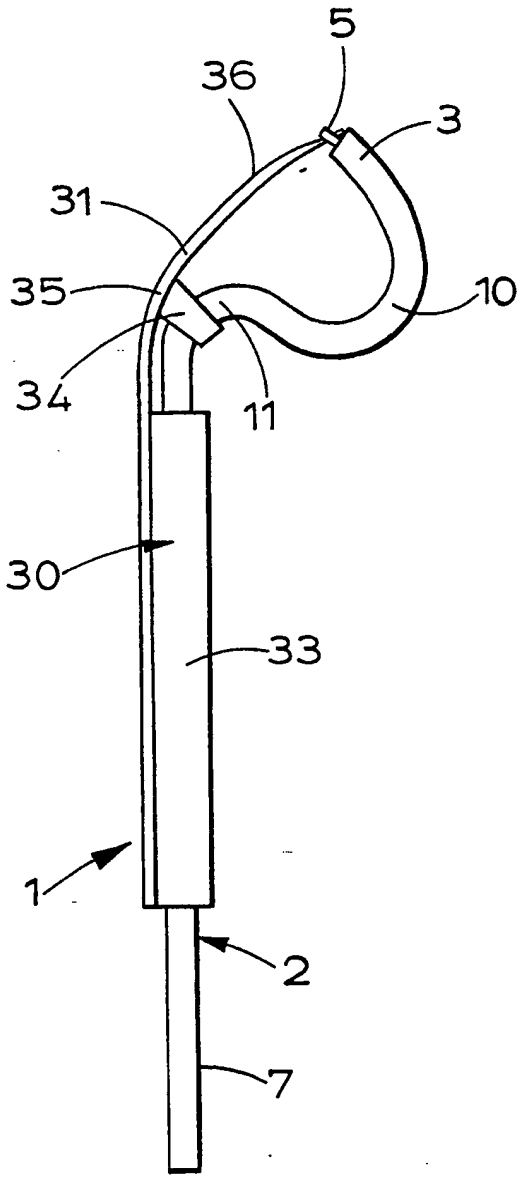

FIG.6.

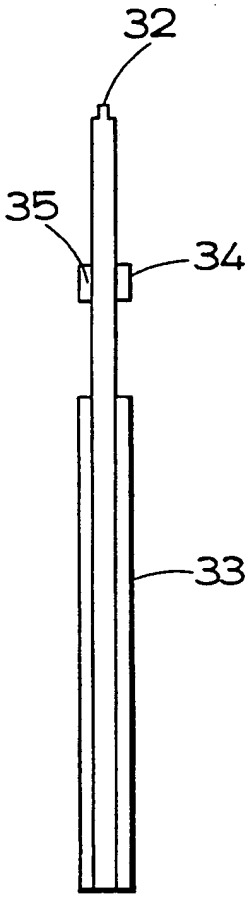

FIG.7.

INTERNATIONAL SEARCH REPORT

PCT/GB 92/00516

International Application . .

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B17/068; A61B17/42

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
A	US,A,3 580 313 (MCKNIGHT) 25 May 1971 see column 4, paragraph 2; figure 7	1
A	US,A,4 462 395 (JOHNSON) 31 July 1984 see abstract; figure 3	1
A	GB,A,2 118 474 (TECHMEDICA) 2 November 1983 see abstract; figure 6	1
A	FR,A,2 445 133 (ANGLADE) 25 July 1980 see claim 1; figure 2	1
A	US,A,3 834 393 (GOGGINS) 10 September 1974	
A	EP,A,0 033 641 (HOWMEDICA) 12 August 1981	
A	GB,A,1 558 965 (NRDC) 9 January 1980	

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"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
26 MAY 1992	11. 06. 92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	BARTON S.

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9200516 SA 57798

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 26/05/92
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-3580313	25-05-71	None		
US-A-4462395	31-07-84	DE-A-	3407084	04-10-84
		JP-B-	3034342	22-05-91
		JP-A-	59164049	17-09-84
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		JP-B-	61038693	30-08-86
FR-A-2445133	25-07-80	None		
US-A-3834393	10-09-74	AU-A-	6905674	20-11-75
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